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EXAMINER	
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ART UNIT	PAPER NUMBER
1643	34

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Below is a communication from the EXAMINER in charge of this application

COMMISSIONER OF PATENTS AND TRADEMARKS

ADVISORY ACTION

☒ THE PERIOD FOR RESPONSE:

a) ☒ is extended to run 6MO or ~~continues to run~~ _____ from the date of the final rejection

b) ☐ expires three months from the date of the final rejection or as of the mailing date of this Advisory Action, whichever is later. In no event however, will the statutory period for the response expire later than six months from the date of the final rejection.

Any extension of time must be obtained by filing a petition under 37 CFR 1.136(a), the proposed response and the appropriate fee. The date on which the response, the petition , and the fee have been filed is the date of the response and also the date for the purposes of determining the period of extension and the corresponding amount of the fee. Any extension fee pursuant to 37 CFR 1.17 will be calculated from the date of the originally set shortened statutory period for response or as set forth in b) above.

☒ Appellant's Brief is due in accordance with 37 CFR 1.192(a).

☒ Applicant's response to the final rejection, filed 8/17/98 has been considered with the following effect, but it is not deemed to place the application in condition for allowance:

1. ☐ The proposed amendments to the claim and /or specification will not be entered and the final rejection stands because:

   a. ☐ There is no convincing showing under 37 CFR 1.116(b) why the proposed amendment is necessary and was not earlier presented.

   b. ☐ They raise new issues that would require further consideration and/or search. (See Note).

   c. ☐ They raise the issue of new matter. (See Note).

   d. ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal.

   e. ☐ They present additional claims without cancelling a corresponding number of finally rejected claims.

   NOTE: _____

2. ☐ Newly proposed or amended claims _____ would be allowed if submitted in a separately filed amendment cancelling the non-allowable claims.

3. ☒ Upon the filing an appeal, the proposed amendment ☒ will be entered ☐ will not be entered and the status of the claims will be as follows:

   Claims allowed: _____
   Claims objected to: _____
   Claims rejected: 60-70

   However;

   ☐ Applicant's response has overcome the following rejection(s): _____

4. ☒ The ~~affidavit, exhibit~~ or request for reconsideration has been considered but does not overcome the rejection because - See attached -

5. ☐ The affidavit or exhibit will not be considered because applicant has not shown good and sufficent reasons why it was not earlier presented.

☐ The proposed drawing correction ☐ has ☐ has not been approved by the examiner.

☐ Other

Advisory Action

1. The arguments and request for consideration has been entered and considered but does not overcome the rejection for the following reasons.

Applicants arguments have been fully considered, but are not persuasive. Applicant argues the rejection made under 35 U.S.C. 112, first paragraph, as lacking written description of the invention, by asserting that a single phrase using the term "synthetic peptide" and the disclosure of a general immunoassay constitutes written description of synthetic peptides of gag, env and pol which are to be used in immunoassays and would be immunoreactive with patient sera. This is not persuasive. Applicant further cites case law concerning the written description of claimed inventions. These arguments are not persuasive, as the issue at hand is that of written description. The determination of whether the specification provides written description of an invention is a question of fact, not a question of law. In the previous office action, statements of fact were set forth indicating that the specification, indeed, does not set forth a written description of the invention *as now claimed.* The '501 specification describes a concept of an invention, not the invention itself. Applicant is quite right in pointing out that the "description of an invention depends on its contend in relation to the particular invention, not its length" as set forth in *In re Hayes Microcomputer Products Inc. Patent Litigation* 982 F.2d 1527 1534 25 U.S.P.Q.2d 1241 1246 (Fed Cir 1992). The position set forth in the previous office action clearly sets forth the content of the '501 specification in relation to the claimed invention, and points out the inadequacies of that disclosure. The specification describes immunoassays using undefined

"fragments" of HIV gene products. The specification at no point sets forth any teaching as to synthetic peptides of env which would be useful in detecting patient sera in immunoassays. Applicant's continual reliance on the Young declaration are not persuasive for the reasons set forth in the previous office actions. Applicant devotes much of the arguments as to whether synthetic peptides were known to be used in immunoassays at the time of the invention. This is not the point of the rejection. The point is that the specification does not set forth synthetic peptides of the env gene which would be useful in immunoassays for detecting anti-env antibodies in patient sera.

In traversal of the enablement rejection, Applicant continues to rely on the Hopp algorithm as expounded in the Young declarations for support that the '501 application fully enables the production of synthetic env peptides *which would be immunoreactive with AIDS patient sera* in the claimed immunoassays. These arguments are not persuasive. The Hopp algorithm simply gives potential starting points for the synthesis of synthetic peptides. Even having potential starting points, one would have been entirely unsure as to whether that starting peptide would have allowed one to detect specific antibodies in patient sera. Applicant asserts that the specification provides "ample teachings regarding the use of peptides in immunoassays"(p6). This is not true. The '501 specification sets forth the use of recombinantly produced, allegedly full length envelope proteins, which are <u>not</u> synthetic peptides. In asserting that the lack of working examples in not indicative of non-enablement, Applicant again relies on the Young declaration. These arguments are not persuasive for the reasons set forth in previous discussions of the Young

declaration. The examiner disagrees with Applicant's statement that the "Patent Office dismisses Applicants' contribution to this art". The contribution to the art is not minimized at all, however the contribution to the art, i.e. the cloning of a new retrovirus, is not enabling for the invention *as it is now claimed.* Applicant argues that using synthetic peptides in immunoassays was known in the art at the time of the invention. This statement is beside the point. The point is that the specification does not give one of ordinary skill in the art, synthetic peptides which would bind AIDS specific antibodies in patient sera in the claimed immunoassays. Applicant cites *In re Cavallito and Gray* in support of the breadth of the pending claims. The cited passage reads "the selection of the examples and other exemplary material used as the disclosure to support a claim must be adequately representative of the area covered by it." The '501 specification does not disclose any examples or any other exemplary material related to synthetic env peptides which would be immunoreactive with AIDS patient sera. In regards to *Genentech*, Applicant is arguing around the point. Applicant continues to argue that the use of synthetic peptides in immunoassays was known. The point of the rejection is that the specification fails to provide synthetic peptides of env which would be immunoreactive with patient sera. The specification does not teach one of ordinary skill in the art how to identify such peptides. The state of the art in regards to immunoreactive portions of the envelope protein was not at such an advanced state that no teachings were necessary to enable the invention as now claimed. (see applicant's own arguments in traversal of the art rejections). Such teachings hardly qualify as "minor omissions" as applied by *Genentech.* Applicant continues to cite the Young declaration and its explanation of the Hopp

algorithm to support the assertions of enablement. Applicant states at page 11 that "the fact that the studies cited in the Young Declaration did not employ the Hopp algorithm is irrelevant to the point which the Declaration makes." The examiner fails to see how failure to utilize a method proves its effectiveness. Finally, Applicant cites an unpublished court decision in support of enablement. Such a citation is improper, and an unpublished decision is not controlling.

As the '501 specification is not enabling for the invention as now claimed, all of the rejections made under 35 U.S.C. 102 and 103 remain.

In traversal of the rejection made under 35 U.S.C. 103 over Schupbach, Sarngadharahan, Popovic, in combination with Levy, and the state of the art as set forth in the Young declaration, Applicant asserts that the state of the art was actually different than that set forth in the Young declaration. This is not persuasive. The state of the art was defined and sworn to by Dr Young. Applicant further appears to be stating that even given the source of the same virus, Levy, "no amount of skill" would have led one to the invention. These arguments further support the rejections made under 35 U.S.C. 112, first paragraph, and further raise new issues as to how Applicant himself employed Levy's isolate.

Finally, in traversal of the rejection made under 35 U.S.C. 112, second paragraph, Applicant points to a portion of the specification discussing recombinantly produced peptides having various lengths. This is not persuasive, as the invention set forth synthetic peptides, and not recombinantly produced peptides.

2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary K Zeman whose telephone number is (703) 305-7133. The examiner can be reached between the hours of 8:00 am and 5:30 pm Monday through Thursday, and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marian Knode, can be reached on (703) 308-4311.

The fax number for this Art Unit is (703) 305-7401.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

mkz
September 10, 1998

MICHAEL P. WOODWARD
PRIMARY EXAMINER
ART UNIT
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